

K 000811

AUG 25 2000

510(k) Summary Statement SLS NLite System

1. General Information

Submitter: SLS Biophile Ltd
Units 1&2 Heol Rhosyn
Dafen Parc
Llanelli, Carmarthenshire
Wales, UK, SA14 8QG

Contact Person: Dr Mike Kiernan – Director of Clinical Research

Summary Preparation Date: March 8th 2000

2. Names

Device Name: NLite System

Primary Classification Name: Laser Powered Surgical Instrument

3. Predicate Devices

- SPTL-1B Pulsed Dye laser, cleared 15/3/1994, K931762 marketed by Candela Inc.,
- Photogenica V Pulsed Dye laser, cleared 8/7/1992, K921842 marketed by Cynosure Inc..

4. Product Description

The NLite System is a flashlamp pumped, pulsed dye laser consisting of the following:

- Main laser console incorporating the laser resonator and external optics, high voltage delivery system, internal cooler, fluid circulation system, control unit and user interface;
- Flexible fibre optic delivery device and optical handpiece;
- Footswitch for pulsing control.

5. Indications for Use

The NLite system is indicated for use in the specialties of Dermatology and Plastic Surgery, and in particular for the treatment of periocular wrinkles.



AUG 25 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Mike Kiernan
Director of Clinical Research
SLS Biophile Limited
Units 1 & 2 Heol Rhosyn
Dafen Parc
Llanelli, Carmarthenshire
Wales, UK SA14 8QG

Re: K000811
Trade Name: NLite System
Regulatory Class: II
Product Code: GEX
Dated: June 16, 2000
Received: June 21, 2000

Dear Dr. Kiernan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

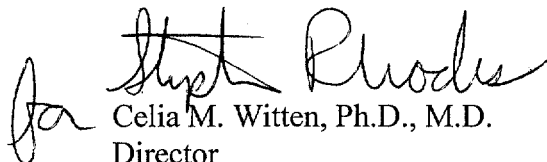
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Dr. Mike Kiernan

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4
Indications for Use Statement as Requested by FDA

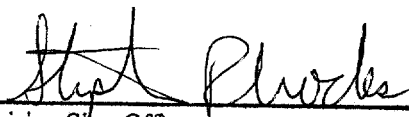
510(k) Number (if known): _____ K000811 _____

Device Name: SLS NLite System

Indications for Use:

The SLS NLite Non Ablative Wrinkle Removal System is indicated for use in Dermatological and Plastic Surgery applications and *this device is intended for use in the treatment of periocular wrinkles.*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____ K000811 _____

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____